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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,446	04/12/2002	Jeff Zablocki	99,423-S	7975

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EXAMINER

CRANE, LAWRENCE E

ART UNIT PAPER NUMBER

1623

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>10/018,446</b>	Applicant(s) <b>Zablocki et al.</b>	
	Examiner <b>L. E. Crane</b>	Group Art Unit <b>1623</b>	

**- THE MAILING DATE of this communication appears on the cover sheet beneath the correspondence address -**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **--3--** MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be filed after six months from the date of this communication.
- If the prior for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 USC §133).

### Status

- ☒ Responsive to communication(s) filed on **-04/15/02 (IDS)-**.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- ☒ Claims **--1-25--** are pending in the application. Claims **-[]-** have been cancelled.
- Of the above claim(s) **--[]-** is/are withdrawn from consideration.
- ☐ Claim(s) **--[]-** is/are allowed.
- ☒ Claims **--1-25--** are rejected.
- ☐ Claim(s) **--[]-** is/are objected to.
- ☐ Claim(s) **--[]-** are subject to restriction or election requirement.

### Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on **-[]-** are ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on **-[]-** is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119(a)-(d)

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) **-[]-**.
- ☒ received in the national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: **-[]-**.

### Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). **--03--**
- ☒ Notice of Reference(s) Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other: **-[]-**

U.S. Patent Trademark Office

### Office Action Summary

PTO-326 (Rev. 06/19/01)  
S. N. 10/018,446

Copy for ☒ FILE ☐ APPLICANT

Paper No. **06**

Art Unit 1623

The disclosure is objected to because of the following informalities: reference has been repeatedly made to physiologically active compounds using only code names and/or acronyms in the disclosure at pp. 33 and 41 (e.g. "NECA," "R-PIA," "CPX," "CGS21680," "HENECA," "YT-186,"  
5 "WRC0470," and "ZM241385"). Applicant is respectfully requested to supply complete chemical structural identification for each of the code-defined chemical substances referred to parenthetically herein as amendments to the disclosure or as a Figure including appropriate Brief Description addition to the disclosure.

10       Appropriate correction is required.

No claims have been cancelled and no preliminary amendments filed as of the date of the instant Office action. An Information Disclosure Statement (IDS) filed April 15, 2002 has been received with all cited references and entered into the case.

15       Claims 1-25 remain in the case.

This application does not contain an abstract of the disclosure as required by 37 C.F.R. §1.72(b). An abstract on a separate sheet is required. The cover sheet of the PCT parent is not an acceptable substitute.

20       Applicant is reminded of the proper content of an abstract of the disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, *e.g.*, "The compounds are of the class of alkyl benzene  
25 sulfonyl ureas, useful as oral anti-diabetics." Exemplifications of a

Art Unit 1623

species could be illustrative of members of the class. For processes, the type of reaction, reagents and process conditions should be stated, and generally illustrated by a single example unless variations are necessary.

5 Complete revisions of the content of the abstract is required on a separate sheet.

10 The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

15 A timely filed terminal disclaimer in compliance with 37 C.F.R. §1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.130(b).

20 Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

25 Claims 1-12 and 19-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,403,567 (PTO-892 ref. B). Although the conflicting claims are not identical, they are not patentably

Art Unit 1623

distinct from each other because the compound claims and related composition and method of treatment claims have a substantial overlap with the claimed subject matter of the noted reference.

35 U.S.C. §101 reads as follows:

5        "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."

10        Claim 25 is rejected under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. §101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. ,1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149, 149 USPQ 475 (D.D.C. 1966).

15        Applicant is referred to the term "useful" in line 1 of claim 25.

20        Claims 1-25 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

25        Claim 1 is directed broadly to a vast array of compounds with multiple substituents nested on substituents only a small fraction of which have been synthesized or shown by applicant to have pharmacological activity. In addition, comparing the examples found in the disclosure of the parent patent, US 6,403,567 (PTO-892 ref. B) with all of the exemplified active ingredients herein includes not a single new example wherein the substituent "R<sub>1</sub>" is a carboxamido group (e.g. -

Art Unit 1623

C(=O)NR<sub>5</sub>R<sub>6</sub>) or wherein such a compound has been subject to any tests of physiological activity. Therefore, the expanded scope of the instant claims when compared with the scope of the issued patent is not justified because the instant disclosure has not enabled any medicinal method of treating with appropriate guidance to indicate the medicinal effect of the substitution of a 5'-amido substituent for the 5'-primary hydroxymethyl group of the '567 patent. See also claim 19, last line wherein the term "mixtures thereof" is directed to subject matter not enabled by any examples found in the instant disclosure. Applicant is respectfully requested to limit the instant claims to subject matter properly enabled by the instant specific embodiments.

Claims 18 and 19 are rejected under 35 U.S.C. §112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 18 defines the variable R<sub>1</sub> in a manner not provided for by claim 10.

Claim 19 makes incorrect reference to the subject matter of claim 1 as a "compound of matter." Applicant is respectfully requested to amend the noted term to read "compound."

Claims 1-25 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 at line 17, the term "alkyl or aryl or heteroaryl amide" appears to be incomplete and is a grammatically incorrect way to refer to a substituent as a compound. Did applicant intend the term to read -- alkyl or aryl or heteroaryl carboxamido -- or

Art Unit 1623

-- alkyl or aryl or heteroaryl sulfonamido -- ? This error reoccurs in claims 1 three times.

In claim 1 at line 20, the term "selected from H, C<sub>1</sub>-C<sub>15</sub> alkyl" is incomplete. Did applicant intend the term to read

5 -- selected from H, and C<sub>1</sub>-C<sub>15</sub> alkyl -- ?

In claim 1 at line 38 the term "wherein optional" is incomplete. Did applicant intend the term to read -- wherein an optional --?

Markush and "or" errors ("and" is present instead of -- or --; Markush group incomplete; etc.) occur

10 in claim 1 at lines 20, 29, 41, and 53; in claim 2 at lines 7, 15; in claim 3 at lines 6 and 12; in claim 4 at lines 8 and 9-10; in claim 5 at lines 9-10; in claim 6 at line 8; in claim 8 at line 8; in claim 13 at lines 7 and 8; in claim 14 at lines 2, 7 and 8; in claim 15 at line 7; and in claim 16 at line 3.

15 In claim 19 applicant is respectfully requested to separate the chemical names of the noted claim with semi-colons (;) and to start a new line (carriage return) in order to clearly separate each name from the remainder of names.

20 In claim 20 at line 1, the term "vasodilatation" is technically incorrect. Did applicant intend the term to read -- vasodilation --.

In claims 23-25 incorrect reference to "the compound of claim 1" when the term should read -- a compound of claim 1 --.

25 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly

Art Unit 1623

owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was  
5 made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must  
10 conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are (703) 308-4556 and 703-305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E.  
15 Crane whose telephone number is 703-308-4639. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Johann Richter, can be reached at (703)-308-  
20 4532.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235.

Serial No. 10/018,446

8

Art Unit 1623

LECrane:lec  
08/25/02

A handwritten signature in dark ink, appearing to read "L. E. Crane", is written over a horizontal line.

L. E. Crane, Ph.D., Esq.

Patent Examiner

Technology Center 1600

5